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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Serial No.: 10/076,937
Filing Date: 02/15/2002
Applicant: Dean, Herbert M. et al.
Title: DOSAGE UNIT FOR CARDIOPROTECTION
Atty. Docket No.: dean0202con
Art Unit: 1617
Examiner: Hui, San-ming R.

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PROVISIONAL ELECTION WITH TRAVERSE PURSUANT TO 37 C.F.R. §1.143

Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the restriction requirement mailed April 23, 2002, Applicants provisionally elect with traverse the Group I invention, identified by the Office as Claims 1-10, but reserve the right to include all of the claims in Groups I, II and III should a generic claim be allowed, pursuant to 37 C.F.R. §1.143, and without affecting Applicants' ability to later file divisional applications based on the non-elected claims of Group II and III.

In the April 23, 2002, Office communication stated that inventions I and II and inventions I and III are related as product and process of use. The Office further stated that the method of treating cardiovascular disease can be practiced with another materially different product such as calcium channel blocker and aspirin, respectively. Applicants respectfully traverse.

Claim 11 of Applicants' disclosure is a dependent claim dependent from Claim 1. The method of Claim 11 requires the use of the medicament claimed in Claim 1. Both

involve a single dosage unit of a beta-adrenergic blocker and a cholesterol lowering agent that is a statin. Even the dependent method claim requires the use of a beta-adrenergic blocker, not a calcium channel blocker. Beta-adrenergic blockers and calcium channel blockers are distinct pharmaceutical entities with different chemical natures and different modes of action.

Beta-adrenergic blockers are different from calcium channel blockers in several ways. Beta-adrenergic blockers are a class of drugs that block beta-adrenergic substances such as adrenaline, a key agent in the "sympathetic" portion of the autonomic (involuntary) nervous system and activation of heart muscle. Beta-adrenergic blockers specifically compete with beta-adrenergic receptor stimulating agents for available receptor sites. Beta-adrenergic blockers slow the heart beat, lessen the force with which the heart muscle contracts and reduce blood vessel contraction in heart, brain and throughout the body. They are also used to improve survival after a person has had a heart attack.

Calcium channel blockers are a class of drugs that block the entry of calcium into the muscle cells of the heart and the arteries. It is the entry of calcium into these cells that causes the heart to contract and arteries to narrow. Calcium channel blockers diminish the contraction of heart and blood vessel muscle by inhibiting calcium ion influx into the cells. Calcium channel blockers are used particularly among patients who cannot tolerate beta-blocking drugs. Unlike beta-blockers, calcium channel blockers have not been shown to reduce mortality or additional heart attacks after a heart attack.

Both Claim 1 and Claim 15 of Applicants' disclosure require the use of a beta-adrenergic blocker and a cholesterol lowering agent that is a statin combined in a single formulation dosage unit. Aspirin is not a substitute for the beta-adrenergic blocker. Aspirin's mode of action is different than that of beta-adrenergic blockers. Unlike beta-blockers, aspirin's effect includes the ability to restrain blood platelets from forming blood clots and therefore keeping them from contributing to heart attacks.

In addition, each of the claims in Groups I, II and III is classified in the very same class (class 513), and in the same subclasses (subclass 277, 415, 423, 460, 510, and 638). Where all of the claims require searching in the same class and subclass, searching for the claims drawn to the medicament will find all relevant prior art for the method claims (dependent and independent) without imposing any serious burden on the Office.

For the above reasons, Applicants respectfully submit that the restriction requirement as to the product and process of use is inapplicable and therefore request that the restriction be withdrawn.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on:

May 21, 2002
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